

REMARKS/ARGUMENTS

Claims 1-5, 7-9, 20-25 and 30-34 are pending. Claims 1 and 20 have been revised to indicate that extraction is performed in an aqueous alkali solution that does not contain a reducing agent. Such a solution is disclosed at pages 8-9 of the specification and in the Examples. While the term “reducing agent” may not find express support in the specification, the present disclosure clearly shows possession at the time of invention of what is now claimed (an aqueous alkali solution not containing a reducing agent). A claim term need not be literally described in the specification.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, **rather than the presence or absence of literal support** in the specification for the claim language (emphasis added)”, In re Kaslow, 217 USPQ 1089 (Fed. Cir. 1983).

New claims 30-33 track and find support in the prior claim language as well as on pages 8-9 of the specification. No new matter has been introduced. Favorable consideration of this amendment and the remarks below and allowance of this case are respectfully requested.

Objection

Claims 26 and 28 were objected to as informal. This objection is now moot.

Rejection—35 U.S.C. §112, second paragraph

Claims 27 and 29 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot.

Rejection—35 U.S.C. §103(a)

Claims 1-5 and 7-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Schrooyen, et al., U.S. Patent No. 7,169,896, in view of Mullner, et al., WO 0236801, English abstract.

Schrooyen does not disclose or suggest a keratin extraction process that does not use a reducing agent. The use of reducing agents denatures the keratin product and results in a less natural product due to disruption of the native disulfide linkages in native keratin. While alkali hydrolysis also breaks disulfide linkages it differs from a process using both alkali hydrolysis and a reducing agent as discussed in detail below.

Mullner (English abstract) was relied upon for teaching a keratinous substrate having a water content ranging from 5% to 99% (see the last lines on page 6 of the OA), but does not teach the elements missing from Schrooyen. Moreover, the English abstract of Mullner does not disclose the range 5% to 99%, is generally directed to extruded protein hydrolysates, and does not mention a method of producing solubilized keratin. The bottom of page 4 of the OA refers to page 4 of Muller as teaching keratin having a water content in the range of 5-99%. The Applicants find no suggestion in Muller for selecting the range 5-99%. While it is noted that page 6 of the German document mentions “Hydrolyse von Keratin” (line 1) and the last paragraph on page 6 refers to “Wassergehalt” which the Applicants understand to mean “water content”, it is unclear where the Examiner finds the suggestion in Muller to select the range 20-80% as required by the present claims.

Nevertheless, even if Muller did teach keratin raw materials having a water content between 5% and 99%, it still did not provide a reasonable expectation of success for the subrange of water content required by the claims, namely 20-80 wt.%. As shown in their Declaration submitted August 31, 2009, selection of a keratin raw material having a water content between 20% and 80% results in superior decomposition by hydrolysis and a substantially better yield of hydrolysate compared to otherwise identical processes using

keratin raw material containing 5%, 15%, 90% or 95% water. Neither Schrooyen, nor Mullner suggested or provided a reasonable expectation of success for this result and can provide no motivation for selecting this range of water content.

The invention of Schrooyen relates to a process for producing *partially modified* and *partially degraded* keratin, and comprises the steps of (a) solubilising keratin from a keratin-fiber containing starting material in an aqueous solution *using a reducing agent* at alkaline pH; and (b) partially modifying the –SH groups of the solubilised keratin, and an optional further hydrolysis step (c) (see claim 1, col. 3; lines 44-52). Schrooyen discloses that partial hydrolysis may be achieved during solubilisation and/or modification (see col. 7; lines 50-51), and further discloses that if solubilisation and/or modification does not produce the desired degree of partial hydrolysis of the solubilised keratin, further hydrolysis or degradation may be achieved by any manner known *per se* in the art, i.e., step (c), see col. 7; lines 51-55. Accordingly, solubilisation with a *reducing agent* and modification of the resulting reduced –SH groups are essential requirement in the production of keratin of Schrooyen to produce partially-modified and partially-hydrolysed keratin.

On the other hand, the claimed invention does not require or employ the reductive step used by Schrooyen and performs the hydrolysis without solubilisation with a reducing agent. Thus, the process of the invention produces a materially different, less denatured and less modified soluble keratin product than the reducing process of Schrooyen.

On page 7, lines 6-9 of OA the Examiner argues that the subsequent modification of Schrooyen can be performed with hydrogen peroxide or acid, which is functionally equivalent to the neutralization step required by the present claims, e.g., the second step in claim 1. However, in the claimed invention, hydrogen peroxide is added in order to adjust the pH to 7.0 or less (around pH 5.0) as a procedure of neutralization after hydrolysis. Further, in the claimed invention, the treatment with hydrogen peroxide is ancillary and not essential to produce the keratin product, in fact, in the Examples 1 and 7, hydrogen peroxide

is not added. Moreover, since the claimed process does not use a reducing agent as does the process of Schrooyen, a lot of free -SH groups are not present in the solubilised keratin produced by the invention in comparison with the free -SH groups required for further modification in Schrooyen, see e.g., col. 5, line 6. Accordingly, the hydrogen peroxide neutralization of the alkali-extracted soluble keratin of the invention differs from the process of Schrooyen which produces significantly more free -SH groups due to prior extraction in the presence of a reducing agent.

When keratin raw material is alkali hydrolyzed to break a cystine (-S-S-) bond (type of disulfide bond), see Nagai, et al., Agr. Biol. Chem. 34:16-22 (attached), it is known that lanthionine¹ cross-linkages and the other cross-linkages are formed, see Asquith, et al., J. Soc. (of Dyers and Colourists) 84:211-216 (attached). Therefore, in the alkali hydrolysis of the invention, lanthionine cross-linkages can form. However, in the Schrooyen process, ***which uses a reducing agent***, while S-S bonds are broken by the reducing agent, a cross-linkage formation such as lanthionine cross-linkages do not occur and the free sulfhydryl (-SH) groups formed by the reduction of disulfide (-S-S-) groups remain. According to the Schrooyen process a free -S-H group is modified with hydrogen peroxide. On the other hand, in the claimed process where -S-S- bonds are hydrolyzed by alkali ***without a reducing agent*** the cleaved bonds are not reduced by a non-existent reducing agent and thus the free -S-H bonds produced by the reducing agent of Schrooyen are not available for modification by subsequent hydrogen peroxide treatment. As a result, the modified keratin produced by the Schrooyen process is **structurally different** than that made by the process of the invention.

These structural differences are further evident from the teachings of Schrooyen. Col. 8, lines 7-14 of Schrooyen describe that at least 99% of the solubilised and partially hydrolysed keratin have a molecular weight of between 3 and 10.4 kDa. If the molecule of

¹ **Lanthionine** is a nonproteinogenic amino acid with the chemical formula (HOOC-CH(NH₂)-CH₂-S-CH₂-CH(NH₂)-COOH). As the monosulfide analog of cystine, lanthionine is composed of two alanine residues that are crosslinked on their β -carbon atoms by a thioether linkage. Despite its name, lanthionine does not contain lanthanum. See Wikipedia, <http://en.wikipedia.org/wiki/Lanthionine> (last accessed August 16, 2010).

solubilised keratins uniformly presents, its average molecular weight should be 6.7 kDa. In addition, Schrooyen, col. 8, lines 15-22, discloses the molecular weight of the solubilised keratin (partially not hydrolysed). It disclosed herein that 15% of the solubilised keratin has a molecular weight less than 10 kDa, which can be interpreted that 85% or more of the solubilised keratin has a molecular weight of 10 kDa or more. While the average molecular weight of the solubilised keratin is not described in Schrooyen, it would be expected to be quite large under the process conditions described by Schrooyen.

The keratin hydrolyzate of Schrooyen has good film formation properties (see col. 15, lines 35-45, Film Formation) and good adhesive properties (col. 15, lines 46-49). However, Schrooyen discloses that a ***major disadvantage*** of solubilised keratins with essentially unmodified cystine/cysteine is that they do not provide keratin-based products, in particular films and coatings, with desired mechanical properties, and such films suffer from brittleness (see col. 2, lines 38-56). Thus, the prior art keratin hydrolyzates produced using reductants are very different in its properties from those of the invention produced without a reducing agent. Accordingly, the effect of the claimed invention is different from that of the Schrooyen invention and would not have been obvious over the Schrooyen process which teaches away from non-reduced and unmodified keratin hydrolysates.

Assuming *arguendo* that one of ordinary skill in the art would have combined the Schrooyen process for obtaining a keratin hydrolyzate by performing the steps of (a) solubilising keratin using a reducing agent at alkaline pH and (b) partially modifying the –SH groups of the resulting solubilised keratin, with the raw material keratin of Mullner having a water content of 5 to 99 wt.%, this combination would not have provided the more natural, unreduced and less denatured solubilized keratin of the invention. That is, exposure of the Mullner raw material keratin to the reducing agent and subsequent exposure to the modifying agents of Schrooyen would have denatured the keratin by reducing the native disulfide bonding, resulting in a more denatured and/or modified product. Consequently, this rejection

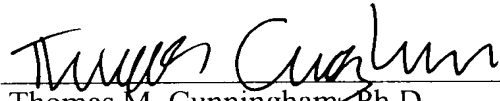
cannot be sustained, because the prior art does not disclose all the elements of the invention, namely extraction of a keratin raw material having a water content of 20% to 80% by weight in an aqueous alkali solution that does not contain a reducing agent, nor does it suggest or provide a reasonable expectation of success for the superior yields and the higher quality, less denatured keratin product made by the claimed process.

Conclusion

This application presents allowable subject matter and the Examiner is respectfully requested to pass it to issue. The Examiner is kindly invited to contact the undersigned should a further discussion of the issues or claims be helpful.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Thomas M. Cunningham", is written over a horizontal line.

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